REMARKS

Applicants' attorney thanks the Examiner for the telephone interview of July 13, 2004. This amendment follows the outcome of that interview. Claims 1-71 were pending original claims in this application. Of these claims, claims 1, 12, 17, 27, 37, 41, 42 and 59 are independent claims. Claims 37-58 are allowed. Claims 1, 12, 17, 27 and 59 have all been amended, as well as some dependent claims. To further the prosecution of this application, amendments and arguments are submitted. Moreover, additional claims (claims 72-102) have been added to this application in order to provide the applicant with the proper and complete scope of claim coverage. All amended claims, as well as added claims are believed to clearly patentably distinguish over the cited prior art. All added claims are believed to be directed to the same invention as originally claimed.

Regarding the rejection of claims 1-36 and 59-71 under 35 U.S.C. 103(a)

Claims 1-36 and 59-71 have been rejected under 35 USC 103(a) as being unpatentable over Daniel et al (U.S. Patent No. 5,860,992) in view of Mizuno et al (U.S. Patent No. 5,876,325). The applicant respectfully traverses this rejection.

To establish a prima facie case for obviousness under 35 U.S.C. § 103(a), (1) there must be some suggestion or motivation to combine reference teachings. (2) There must be a reasonable expectation of success. (3) The references when combined must teach or suggest all the claim limitations. For the reasons discussed below, it is respectfully submitted that the Office has not established a prima facie case under 35 U.S.C. § 103(a) for claims 1-36 and 59-71, and that therefore, claims 1-36 and 59-71are allowable.

Referring to cited prior art Daniel, the Office has referred to Fig. 9A and descriptions in column 3 at lines 30-50 as showing a system for cardiac valve repair including a shaft as shown in Fig. 9A. While Daniel does describe a general cardiac procedure, the teaching in Daniel is limited to a hand-held instrument controlled directly at the instrument shaft and adapted for positioning through an incision in the chest wall, not intraluminally (by "intraluminal" reference is made to within a body lumen or vessel). Refer to column 3 of Daniel at lines 39-41 where access to the thoracic cavity is described as "within intercostal spaces of the patient's rib cage".

The Office acknowledges that Daniel does not teach a flexible guide shaft nor a flexible inner shaft and a remote manipulator controlled from a site remote from the body for controlling the tool. The Office's position is that cited prior art Mizuno teaches these latter elements, although the Office did not refer to any specific sections of Mizuno.

Like Daniel, Mizuno is also primarily directed to the control of an instrument laparoscopically through an incision, such as in embodiments shown in Figs. 1, 14, 26, 48 or 50. Thus, in both Daniel and Mizuno incisions are required in order to provide access of the instrument to internal organs. Although these procedures may be an improvement over open surgery procedures, they still require an incision and associated stress to the patient.

One characteristic of the instrument system of the present invention is the ability to perform a surgical technique, preferably a cardiac surgical technique, without an incision through the abdominal wall or rib cage and preferably by means of passage of the instrument system intraluminally, such as the described example of extending the instrument shaft through the jugular or femoral vein to the heart. This absolutely minimizes stress to the patient and even enables surgical procedures to be performed dynamically (upon a beating heart). Moreover, in accordance with one further aspect of the present invention this intraluminal passage is through a vascular lumen, something that is neither taught nor suggested by either Daniel or Mizuno alone or in combination. Although Fig. 39 of Mizuno describes a medical procedure in the aorta, all instruments are disposed outside the aorta, and there is absolutely no teaching of vascular intraluminal passage of instruments. Moreover, the embodiment in Fig. 38 of Mizuno does not teach telerobotically controlled intraluminal insertion of an instrument tool for a cardiac procedure.

Moreover, neither Daniel nor Mizuno shows the use of a guide tube or guide shaft used as a means for supporting and guiding therethrough an instrument shaft, both of which are independently telerobotically operated. Thus, another characteristic of the instrument system of the present invention, clearly not taught by Daniel or Mizuno, is the ability to use a guide tube or guide shaft for supporting and guiding, or threading therethrough, an inner instrument shaft, particularly where the instrument system is used in or through a vascular lumen and is operated telerobotically from an input device at a user interface that is remotely controlled by a medical practitioner.

The Office has cited Mizuno for showing a system with a flexible guide shaft and a flexible inner shaft. However, the Office has not pointed out how Mizuno teaches this claim limitation because no reference has been made in the Office Action to any specific sections of Mizuno that teach such a system. The Office merely indicates that the limitations are shown in the figures of Mizuno.

The Applicants have carefully examined Mizuno and in particular an embodiment of an instrument shown in Figs. 56-59. The instrument described by Mizuno, although operated telerobotically, is primarily meant for a laparoscopic application (*see* Fig. 50 of Mizuno and the trocars 530 for coupling instruments to the abdominal cavity 514) and does not use the technique of the present invention in which the instrument shaft is meant for support in and guidance or threading through an outer guide shaft through a vascular lumen in performing a surgical procedure. Referring to Fig. 56, a bending mechanism 537 is operated from an actuator 541 in instrument 520, via cables or wires 539 and 540. A rod 542 intercouples rod 544, flexible rod 543 and forceps 517, and is operated from the actuator 551 of instrument 520 for control of the operation of the forceps. (*See* Col. 35-41.) Elements 537 and 542 are always in the same fixed positional relationship therebetween, as parts of a fixed instrument structure. Element 537 does not function as a "guide" for the instrument shaft, and again, there is no teaching of intraluminal passage, particularly for cardiac procedures through a vascular lumen.

The basic instrument shown in Figs. 56-59 of Mizuno is a rigid instrument. It has to be rigid in order to pass through a trocar for proper positioning in the abdominal cavity. As such it is not at all useable for passage through an anatomic lumen. Although Mizuno discusses a bending mechanism 537, the rest of the instrument shaft is in the form of a "pipe 538" that must be rigid to operate properly. Mizuno does not teach an inherently flexible or deformable shaft adapted for passage through an anatomic lumen, reference in Mizuno is to a technique in a "body cavity". For example, in Mizuno the second, fifth and sixth objects are set out in columns 3 and 4. In a body cavity a rigid instrument is necessary, but not so for intraluminal use.

Thus, the references when combined do not teach or suggest all of the claim limitations. Furthermore, there is no suggestion or motivation to combine reference teachings. The teaching or suggestion to make the claimed combination must be found in the prior art. (*See* MPEP 2142.)

There certainly is no suggestion in Daniel to operate the device telerobotically. Although the Mizuno instrument system is telerobotic there is no suggestion that telerobotics can be applied to a heart valve procedure, particularly where the operative instrument is delivered to the operative site through a lumen of the subject's vascular system.

Still another feature of the present invention is the ready ability to exchange inner instrument shafts while leaving the guide shaft in place. Certainly, this feature is not taught in Mizuno rod 544 and outer shaft pipe 538 are fixed in position with no interchange therebetween. This ability to remove and replace instruments is important in efficiently performing a medical procedure. An example is found in the present application in Figs. 30, 30A and 30B where three different inner catheter structures are shown (155, 172 and 182). Fig. 30A shows the crimping catheter 172 which is removed after it is used and replaced by the cutting catheter 182 shown in Fig. 30B.

With the above distinguishing features in mind, the Applicants have made amendments in the claims to clarify the Applicants' invention. All claims in the application, including added claims, should now be in condition for allowance.

Independent Claim 1 has been amended to recite that the inner shaft is received in and removably threaded through the guide shaft. This is not taught by the combination of Daniel and Mizuno. Claim 1 has also been amended to add the "user interface". Claims 2-11 are dependent on Claim 1 and thus include this limitation over the prior art.

Claim 12 has been amended to recite that the guide catheter extends intraluminally through a vascular vessel, and that the flexible working catheter is not only received by but also threaded through the guide catheter. This is not taught by either Daniel or Matsui either singly or in combination. Claim 12 has also been amended to recite that the remote manipulator is controlled by a user. Claims 13-16 are dependent on Claim 12 and thus include this limitation over the prior art.

Claims 17 and 27 are directed to a method. Claim 17 has been amended to recite that the guide shaft extends through a vascular vessel. Daniel or Matsui either singly or in combination do not teach or suggest all of the steps of the claimed method. For example, with regard to claim 17, the prior art does not teach or suggest extending a guide shaft through a vascular vessel from a site outside the patient to a site adjacent the mitral valve, nor inserting a fiber through the guide

shaft. The same can also be said of method claim 27 that includes steps of extending a guide shaft from a site outside the patient intraluminally to a site about the mitral valve, and providing a ring of a first diameter, the ring being deformable and capable of matching a desired predetermined diameter of an annulus of the mitral valve, the ring engaged with the guide shaft via a flexible inner shaft received by and threaded through the guide shaft. Claims 18-26 are dependent on Claim 17 and claims 28-36 are dependent on claim 27 and thus include this limitation over the prior art.

Claim 59 is also distinguishable over Daniel and Matsui for reasons previously stated. Claim 59 recites that there is an instrument shaft having sufficient flexibility along a length thereof so as to readily flex and conform to a vascular lumen pathway in the anatomy as the shaft is inserted therein. Claim 59 further states that the instrument shaft is insertable into a subject threaded through a flexible guide shaft so as to dispose the distal end of the instrument shaft at an internal site of an anatomic body part. These limitations are not taught by either Daniel or Mizuno or a combination thereof. Claims 60-71 are dependent on Claim 59 and thus include this limitation over the prior art.

Accordingly the rejection under § 103(a) is believed to be overcome.

The applicant has also added claims 72-102 to this application. Support for the newly added claims 72-102 is in the applicants' specification as originally filed. (*See* claims 21-23; Page 17, lines 16-25; Page 19, line 15 – Page 20, line 2; Page 43, lines 8-10; Page 24, line 15.) Claims 72-84 are dependent from original independent claims and as such should be found allowable for the same reasons as argued regarding the independent claims, as well as for the added limitations in each dependent claim.

Independent claim 85 defines a flexible guide shaft extending from a site outside a patient through an anatomic vascular lumen to the area of the operative site; an inner flexible instrument shaft supporting at its distal end a tool that is controllable in assisting in the medical procedure; and wherein the inner flexible instrument shaft is received in and threaded through the guide shaft for disposing the tool at the operative site. Claim 85 also recites a user interface and a controller as set forth. Claims 86-90 are dependent on claim 85 and thus include these distinguishing features in addition to other features clearly not taught by the cited prior art.

Independent claim 91 directed to a method defines steps of extending a flexible guide shaft from a site outside a patient through an anatomic vascular lumen to the area of the operative site; threading an inner flexible instrument shaft, that supports at its distal end a tool that is controllable in assisting in the medical procedure, through the guide shaft for disposing said tool at said operative site; manipulating a user interface at which a medical practitioner manipulates an input device; and providing a controller coupled between the user interface and a drive for at least one of the shafts, and that receives a command from said input device for controlling at least one of said shafts so as to respond in accordance with action at the input device in performing the medical procedure. This method is not taught or suggested by Daniel and Matsui whether they are taken singly or in combination. Claims 92-94 are dependent on claim 91 and thus should also be found allowable.

Independent claim 95 should also be found allowable for the same reasons as claim 85. In addition claim 95 also includes means for detecting, as stated, not taught or suggested by Daniel and Matsui whether they are taken singly or in combination. Claims 96-102 depend from claim 95 and should also be found allowable.

Information Disclosure Statement

An Information Disclosure Statement (IDS) is being filed concurrently herewith. Entry of the IDS is respectfully requested.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By Caroline M Fleming

Caroline M. Fleming
Registration No. 45,566
Telephone: (978) 341-0036
Facsimile: (978) 341-0136

Concord, MA 01742-9133
Dated: 8/5/04